

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**



(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:  
16.06.1999 Bulletin 1999/24

(51) Int. Cl.<sup>6</sup>: **A61K 31/00**, **A61K 7/50**,  
**A61K 7/00**, **A61L 15/34**,  
**A61F 13/15**

(21) Application number: **97120700.6**

(22) Date of filing: **26.11.1997**

(84) Designated Contracting States:  
**AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC**  
**NL PT SE**  
Designated Extension States:  
**AL LT LV MK RO SI**

(72) Inventors:  
• **Palumbo, Gianfranco**  
**61348 Bad Homburg (DE)**  
• **Guarracino, Mario**  
**64028 Silvi Marina (Teramo) (IT)**

(71) Applicant:  
**THE PROCTER & GAMBLE COMPANY**  
**Cincinnati, Ohio 45202 (US)**

(74) Representative:  
**Canonici, Jean-Jacques et al**  
**Procter & Gamble European Service GmbH,**  
**Sulzbacher Strasse 40-50**  
**65824 Schwalbach am Taunus (DE)**

(54) **Skin care composition**

(57) The invention relates to compounds to be used for preparation of compositions, which can be applied to the skin to prevent or reduce or treat skin rash or diaper rash resulting from lipolytic dermatitis. The compositions can be in the form of cosmetic lotions, creams, powders, oils, foams and the like. The compositions can also be applied to diapers, incontinent-pads, wipes and the like.

The invention also relates to the use of such a composition to prevent or reduce such a skin rash and a process for reducing the lipolytic enzyme activity of lipase enzymes present on external skin.

**Description**

[0001] The invention relates to compounds to be used for preparation of compositions, which can be applied to the skin to prevent or reduce or treat skin rash or diaper rash resulting from lipolytic dermatitis. The compositions can also be in the form of lotions, creams, powders, oils, foams and the like. The compositions can also be applied to diapers, incontinent-pads, wipes and the like.

[0002] The invention also relates to the use of such a composition to prevent or reduce such a skin rash and a process for reducing the lipolytic enzyme activity of lipase enzymes present on external skin.

**Background**

[0003] Skin rash caused by dermatitis, often referred to as diaper rash, has always been a problem encountered by the users of disposable absorbent articles, such as diapers, incontinence articles, sanitary towels, training pants etc. Therefore, one of the biggest needs for these users is a solution to this type of skin rash problem.

[0004] The main factor which influences the development of skin rash is the contact of the skin with the wet body exudates, directly or for example contained in the absorbent article. Especially when the water content is high, skin rash can occur easily.

[0005] Manufacturers of diapers and skin care products have developed various products over the past decades which help reduce the occurrence of diaper rash (or skin rash).

[0006] The main focus thereby has been to reduce the exposure of the skin to the body exudates. This is for example done by introduction to the diaper of absorbing or better absorbing materials. The amount of water which is in contact with the skin is thus reduced.

[0007] Other products which are developed to address the skin-rash problem reduce the exposure of the skin to certain ingredients of the body exudates. An example of such ingredients of the exudate are bacteria which can infect the skin and thus start off or aggravate the skin rash.

[0008] For example, lotions have been developed which can form a barrier between the skin and the body exudates. Also, anti-inflammatory compositions can be applied to the skin or absorbent article.

[0009] EP 0191128 discloses a preparation comprising 8-hydroxy quinoline sulphate for treatment of skin irritation.

[0010] However, still one of the most heard complaints amongst users of absorbent articles such as diapers is the persistence of skin or diaper rash, despite the numerous products on the market which can be applied to prevent diaper or skin rash.

[0011] It has been discovered that yet another factor can set off or aggravate skin rash, namely the presence, in the body exudate of various enzymes, especially lipase and protease enzymes.

[0012] EP 0117632-B relates to disposable articles which comprise lipase inhibiting agents, preferably zinc containing components, and a vehicle material.

[0013] US 3,091,241 relates to the use of triacetine in vaginal tampons to inhibit lipase enzyme activity.

[0014] US 3,961,486 teaches the use of adipic acid to reduce the lipase enzyme activity and to reduce the skin rash.

[0015] When the skin is exposed to lipase enzymes, the lipids of the skin can be affected by these enzymes. The protection or barrier function of the top layer of the skin (the Stratum Corneum) will thus be diminished. This can effect the health of the skin and/or facilitate the infection of the skin. This can thus lead to skin or diaper rash.

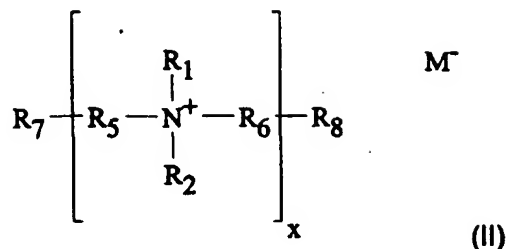
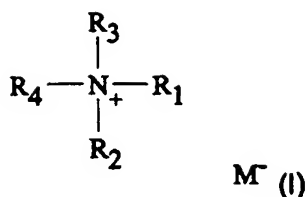
[0016] It is known that bile salts are present in the body exudates. These bile salts are known to emulsify the lipids in the body, which ensures that the lipase enzymes are capable of performing on the lipid/ water interface. The inventors have now found that these bile salts still have an emulsifying function once outside the body. They then continue to aid the lipase enzyme which is also present in the body exudate by attacking the lipids in the outer layer skin, exposed to the body exudate.

[0017] The inventors have found that these bile salts can be inactivated (and thereby the lipase can be deactivated) when the salts are reacted with specific cationic compounds. The inventors have found that the cationic compounds can thereto be applied to the skin by introduction of the cationic compounds into a composition, cream, lotion, foam, oil, powder which is to be applied directly to the skin or which can be applied to an absorbent article, such as a diaper, which can be applied to the skin..

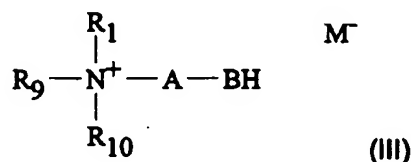
[0018] It has been found that the use of these cationic compounds very effectively reduces or helps to prevent or treat the diaper/skin rash, resulting from dermatitis caused by lipase enzymes. Thus, a process for reduction of the lipolytic enzyme activity of lipase enzymes on the external skin is thus provided and encompassed herein.

**Summary of the invention**

[0019] The invention relates to the use of one or more cationic compounds of formulas:



or an amphoteric compound and preferably an acidity source, the amphoteric compound having at its iso-electric point the formula:



for preparation of a composition for treatment, prevention or reduction of lipolytic dermatitis of the external skin, wherein  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  are independently a  $C_1$ - $C_{22}$  alkyl, alkenyl, aryl, arylalkyl, amidoalkyl, (poly) alkoxy, hydroxyalkyl, or acyl groups, or two or more groups of  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  form together one or more ring structures;  $R_5$ ,  $R_6$  and  $A$  are independently a  $C_1$ - $C_{22}$  alkylene, alkenylene, (poly) alkoxy, hydroxyalkylene, arylalkylene or amido alkylene groups;  $R_7$  and  $R_8$  are independently a  $C_1$ - $C_4$  alkyl, alkenyl, alkoxy group or a hydroxy group or hydrogen;  $R_9$  and  $R_{10}$  are independently a  $C_1$ - $C_{22}$  alkyl, alkenyl, aryl, arylalkyl, amidoalkyl, (poly) alkoxy, hydroxyalkyl, or acyl groups, or two or more of the groups  $R_1$ ,  $R_9$  and  $R_{10}$  form together one or more ring structures;  $BH$  is a proton donating group;  $x$  is from 2 to 4; and  $M^-$  is a counter ion.

[0020] The invention also provides a disposable absorbent article, preferably a diaper, containing the composition as described above, preferably at such a level that the cationic compounds therein are present at a level of from 0.01% to 10% by weight of the article, preferably comprised in the topsheet of the diaper.

[0021] The invention also provides compositions being cosmetic compositions in the form of a cream, foam, lotion, gel, oil, ointment or powder for treatment, prevention or reduction of lipolytic dermatitis of the external skin. These compositions preferably comprise preferred cationic compounds above, namely wherein the cationic compound comprises one or more substituted  $R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ ,  $R_9$  or  $R_{10}$  groups and/or a substituted  $R_5$  and/or substituted  $R_6$  group, whereby the substituent is selected from the group from the group consisting of derivatives of silicon, glucose, fructose and saccharose, whereby the compositions are substantially free from nonionic and/or anionic surfactants and/or phosphoric acid esters and/or enzymes for topical application to the external skin.

#### Detailed Description of the Invention

[0022] The cationic compounds are used for the preparation of compositions for prevention, reduction or treatment of lipolytic dermatitis of the (external) skin.

[0023] By treatment or reduction is meant herein the reduction of the dermatitis or the rash of the skin which is caused

by lipolytic enzymes, or at least stabilising the dermatitis or rash of the skin which is caused by lipolytic enzymes.

[0024] The composition of the invention can be directly applied to the skin which is in contact with lipolytic or lipase enzymes. Such compositions can be comprised in cosmetic composition, being in the form of a cream, lotion, foam, oil, ointment, powder or gel, which can be topically applied to the skin.

5 [0025] Alternatively, the compositions of the invention can be applied to an absorbent article, which can be brought in close contact with the skin which is in contact with the lipolytic enzymes. Such articles are preferably disposable articles such as diapers, incontinent pads, training pants, sanitary towels, feminine hygiene garments, dry or wet wipes.

[0026] By the term "topical application" or "topical(ly) applied", as used herein, is meant directly laying on or spreading on epidermal tissue, especially outer skin.

10 [0027] The amount of the composition comprising the cationic compounds of the invention will vary with the particular location of the condition being treated, the severity of the condition being treated, the expected duration of the treatment, any specific sensitivity to either the composition itself, or the concentration of the lipase-inhibiting agent specific to the user, the condition of the user, concurrent therapies being administered, other conditions present in the user.

15 [0028] For the present invention it is preferred that a minimum inhibitory concentration of the compositions containing the cationic compound is topically applied, to act as a bile salt-inhibiting composition to the area in need of treatment of the lipolytic dermatitis or the area where prevention of lipolytic dermatitis is desired in a form such that it is available to inhibit the activity of the lipase present.

20 [0029] This area (or "affected area", as used herein) is meant the area of the skin which is presently exhibiting any levels of skin rash or lipolytic dermatitis, or the area which will be in prolonged contact with body exudates containing lipase enzymes and bile salts. This also includes the area immediately proximate to the described area. It is the area at which treatment, reduction of, and /or prevention is desired.

#### Lipolytic dermatitis

25 [0030] This invention deals with compositions (or (disposable) absorbent articles incorporating the compositions of the invention) for the treatment of skin or diaper rash or diaper dermatitis caused by lipase enzymes present in the body exudates (thus lipolytic dermatitis), and other conditions which are associated with prolonged contact of the skin with body exudates and/or the wearing of a absorbent article, or in particular a diaper.

30 [0031] Lipase, lipase enzymes or lipolytic enzymes is the trivial or common term employed to represent what is in fact a group of enzymes belonging to the esterases. Their general activity is to hydrolyze fats present in the ester form (such as the glycerides found in human skin), and accordingly generate fatty acids and glycerol. Because this group of enzymes is so widely distributed in plants, moulds, bacteria, milk, and milk-products, as well as in almost all animal tissues, and because moreover human lipase enzymes are present in the pancreatic exudates, they are almost always present in body exudates.

35 [0032] The activity of lipase contributes to almost all skin rash or in particular diaper rash, causing irritation by the digestive degenerative action of lipase on the skin per se and by breaking down the lipid skin-components compromises the barrier property of the skin in the affected area. This breakdown of the integrity of the skin allows other components of the body exudates (urine and faeces in particular), which may not, by themselves, be irritating, to migrate through the compromised skin. At this point normally harmless components may then become irritating.

40 [0033] The lipase has been found to be activated by the presence of pancreatic bile salts, which are present in the body exudates. The bile salts function as emulsifiers of lipids, enabling the lipase enzymes to act on the water-lipid interface.

45 [0034] When employing the compositions of the present invention, the bile salts are inactivated and thus the lipase is inactivated. It is thereby prevented from acting upon the skin and causing irritation. Such inactivation of lipase prevents the compromise of the barrier function of the skin which in turn prevents irritants (such as fungi, bacteria, and bile salts and acids) from migrating through and further irritating and inflaming the skin.

#### Compositions

##### 50 Cationic compounds

[0035] The present invention provides specific cationic compounds, as defined above for use in the preparation of compositions which can be used for treatment, prevention or reduction of the skin rash or particularly diaper rash, which is set off or aggravated by lipase or lipolytic enzymes, thus being the result of lipolytic dermatitis.

55 [0036] It should be understood that for the purpose of this invention, the groups  $R_1$ - $R_{10}$  of formulations (I), (II) and (III) above can be substituted by any appropriate substituent group.

[0037] In the formulations above,  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_9$  are independently preferably  $C_1$ - $C_8$ , more preferably  $C_1$ - $C_4$  alkyl or alkoxy, more preferably alkyl groups, most preferably methyl or ethyl groups.

[0038] Preferably, R<sub>4</sub>, R<sub>5</sub> and R<sub>10</sub> are independently C<sub>8</sub>-C<sub>18</sub>, more preferably C<sub>12</sub>-C<sub>16</sub> alkenyl or alkoxy, more preferably alkyl or arylalkyl groups, whereby it can be preferred that one of the R<sub>4</sub>, R<sub>5</sub> and R<sub>9</sub> substituents is benzyl group.

[0039] Alternatively, it can be preferred that the cationic compound comprises at least one R<sub>1</sub>, R<sub>2</sub> or R<sub>3</sub> or R<sub>9</sub> being a poly alkoxy group.

5 Thus, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>9</sub> preferably are independently polyalkoxy groups comprising C<sub>2</sub>-C<sub>6</sub>, preferably C<sub>2</sub>-C<sub>3</sub> alkoxy units and having an alkoxylation number of from 2 to 50, preferably from 5 to 18. Then, R<sub>3</sub>, R<sub>4</sub> and R<sub>10</sub> are independently preferably C<sub>1</sub>-C<sub>8</sub>, more preferably C<sub>1</sub>-C<sub>4</sub> alkenyl or alkoxy, more preferably alkyl groups, most preferably methyl or ethyl groups.

[0040] A, R<sub>5</sub> and R<sub>6</sub> are, independently, preferably C<sub>1</sub>-C<sub>6</sub> alkenylene or more preferably alkylene groups, most preferably methylene or ethylene.

[0041] Preferred compounds can be benzalkonium chloride or Merquat 2200 (Trade name, being a 2-Propeneamide polymer of N,N-dimethyl-N-2-Propenyl-1-ammonium chloride).

[0042] Preferred cationic compounds of the formulas above comprise one or more substituted R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>9</sub> or R<sub>10</sub> groups and/ or a substituted R<sub>5</sub> and/or substituted R<sub>6</sub> group, whereby the substituent is selected from the group from the group consisting of derivatives of silicon, glucose, fructose and saccharose.

15 Preferred can be Glucquat 125 (trade name, being lauryl dimethyl glucet-10-hydroxydimonium chloride).

[0043] Preferred cationic compounds of the formula (III) above are betaine or sulpho betaine having preferably R<sub>1</sub> and R<sub>9</sub> being a methyl group.

[0044] The composition preferably comprise the cationic compounds at a level of from 0.01% to 90%, more preferably from 0.5% to 60%, most preferably from 2% to 25% by weight of the composition.

20 [0045] The compositions can be prepared by any conventional formulation technique known in the art.

#### Additional ingredients

25 [0046] The composition of the invention can comprise additional ingredients. Which ingredient are present and in which level depends on the character of the composition and the use thereof.

[0047] A highly preferred additional component to be used for the preparation of the compositions of the present invention or for use in the compositions of the present invention are certain ester compounds.

30 [0048] These esters can function as enzyme substrates, which, when acted upon by a hydrolyzing enzyme, such as lipase enzymes will be hydrolyzed resulting in the release of free acids. The presence of these acids will lower the pH of the area where the esters were topically applied to. This will amount to inactivation of all or most enzymes present in this area, in the body exudates, such as the lipase enzymes, protease enzymes, which can all affect the skin, resulting in irritation or skin rash.

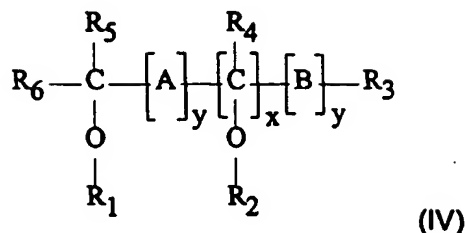
35 [0049] In the compositions of the present invention the use of such ester compound has been found to have a surprising effect: it has been found that the cationic compounds provide an immediate effect, i.e. immediate inhibition or inactivation of the lipase enzymes, which may reduce over time, whilst the effect of the ester compounds is relatively delayed but long-lasting. Thus, the combination of the two compounds provides an very effective, immediate and long-lasting reduction or prevention of the diaper/skin rash, resulting from dermatitis caused by the enzymes present on the body exudates on the skin.

40 [0050] A highly preferred ester compound for use in, or for preparation of the compositions of the invention is of the formulation:

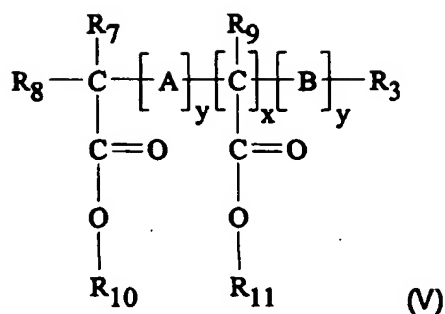
45

50

55



or



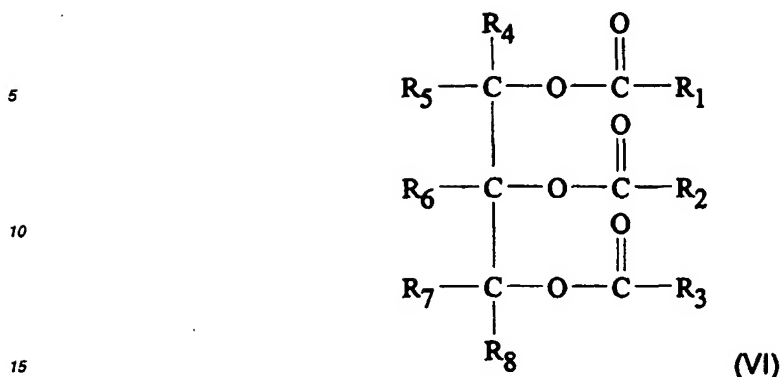
wherein  $\text{R}_1$  and each  $\text{R}_2$  independently are an acyl group with from 2 to 22 carbon atoms, or an alkyl, alkenyl, arylalkyl, hydroxyalkyl group with from 1 to 24 carbon atoms or hydrogen, whereby at least one of  $\text{R}_1$  and  $\text{R}_2$  is such an acyl group,  $\text{R}_3$ ,  $\text{R}_4$ ,  $\text{R}_5$ ,  $\text{R}_6$ ,  $\text{R}_7$ ,  $\text{R}_8$ , and  $\text{R}_9$  are independently an alkyl, alkenyl, arylalkyl, hydroxyalkyl, alkoxy groups of from 1 to 24 carbon atoms, hydroxy group or hydrogen;  $\text{R}_{10}$  and  $\text{R}_{11}$  are independently an alkyl, alkenyl, arylalkyl, hydroxyalkyl, alkoxy groups of from 2 to 24 carbon atoms, hydroxy group or hydrogen; A and B are independently a  $\text{C}_1$ - $\text{C}_6$  linear or branched alkylene, alkenylene, alkoxyethylene, hydroxyalkylene groups; the values of x are independently from 0 to 15; the values of y are independently 0 or 1, with the proviso that when  $x=2$  and  $y=0$ , at least one  $\text{R}_2$  is an alkyl, alkenyl, arylalkyl, hydroxyalkyl group with from 1 to 24 carbon atoms or hydrogen

[0051] Preferred are the ester compounds as defined above, wherein the compound is of formula (IV) or (V) wherein x is 1 or 2, y is 0;  $\text{R}_1$  and one  $\text{R}_2$  are a  $\text{C}_2$ - $\text{C}_{16}$  acyl group,  $\text{R}_{10}$  and one or more  $\text{R}_{11}$  are a  $\text{C}_2$ - $\text{C}_{16}$  alkyl group;  $\text{R}_3$ ,  $\text{R}_4$ ,  $\text{R}_5$ ,  $\text{R}_6$ ,  $\text{R}_7$  and  $\text{R}_8$  are hydrogen

[0052] It is highly preferred that the additional ester compound is a mono or diester of formula (V), most preferably a mono or diester of citric acid or tartaric acid (or salts thereof), or a triester of citric acid.

[0053] Another highly preferred ester compound of formula for use in the preparation of the compositions of the present invention or for use in the compositions can be an ester compound of the formulation:





wherein R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> are independently an alkyl or alkenyl or hydroxyalkyl group with from 1 to 22 carbon atoms, and R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub>, R<sub>7</sub> and R<sub>8</sub> are independently selected from the group consisting of C<sub>1</sub>-C<sub>10</sub> linear or branched alkyl, alkenyl or hydroxyalkyl groups, hydroxy, chloride, bromide, amine or hydrogen.

[0054] Highly preferred are the compounds above wherein R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub>, R<sub>7</sub> and R<sub>8</sub> of said compound are hydrogen and preferably wherein R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> are independently an C1-C4 alkyl group.

[0055] Such a preferred compound can be glycerol triacetate.

[0056] The additional ester compounds are preferably present in the compositions of the invention at a level of from 0.01% to 20%, more preferably from 0.05% to 10%, most preferably from 0.1% to 5% by weight of the composition.

#### Lotions, creams, oils, foams, ointments, gels, powders and the like

[0057] The compositions of the invention can be cosmetic compositions in the form of lotions, creams, oils, foams, ointments, powders, gels. They can comprise any of the ingredients commonly used in the art for such compositions.

[0058] Preferred cosmetic compositions are prepared by use of cationic compounds as described above, wherein the cationic compound comprises one or more substituted R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>9</sub> or R<sub>10</sub> groups and/ or a substituted R<sub>5</sub> and/ or substituted R<sub>6</sub> group, whereby the substituent is selected from the group from the group consisting of derivatives of silicon, glucose, fructose and saccharose, whereby the compositions are substantially free from nonionic and/ or anionic surfactants and/ or phosphoric acid esters and/ or enzymes for topical application to the external skin.

[0059] It is to be understood that the ingredients of the compositions above will depend on the character of the composition, thus lotions will generally comprise different additional ingredients than powders.

[0060] In the cosmetic creams, lotions, gels, oils or powders comprising the composition of the invention preferably an acidity source is present, preferably such that is capable to reduce the pH of the skin to below a pH of 8, more preferably below a pH of 7, more preferably below a pH of 6, or even more preferred below a pH of 5.

[0061] It can be preferred that the cosmetic cream, lotion, gel, oil, ointment or powder are substantially free from non-ionic and/ or anionic surfactants and/ or phosphoric acid esters and/ or enzymes.

#### Absorbent Articles

[0062] The compositions of the present invention can be comprised in an absorbent article, preferably a disposable absorbent article. A particularly preferred absorbent articles therefor is a wipe or a diaper. The diaper preferably comprises the composition in the topsheet of the diaper.

[0063] As used herein, the term "absorbent articles" refers to devices which absorb and contain body exudates, and, more specifically, refers to devices which are placed against or in proximity to the body of the wearer to absorb and contain the various exudates discharged from the body. The term "disposable" is used herein to describe absorbent articles which are not intended to be laundered or otherwise restored or reused as an absorbent article (i.e., they are intended to be discarded after a single use and, preferably, to be recycled, composted or otherwise disposed of in an environmentally compatible manner).

[0064] The structure of the disposable absorbent article is not critical to the practice of the present invention.

[0065] Normally, the composition is incorporated into the absorbent article or diaper in particular in an amount which

will deliver the required treatment or reduction or prevention of the lipolytic dermatitis preferably after frequent use.

[0056] The disposable absorbent article preferably contains the composition according to the invention at a level such that the cationic compounds therein are present at a level of from 0.01% to 30%, more preferably from 0.01% to 10%, most preferably from 0.05% to 5% by weight of the article.

5 [0057] An absorbent article generally comprises

- an absorbent core (which may consist of sub-structures);
- a fluid pervious topsheet;
- a fluid impervious backsheet;
- 10 - optionally further features like closure elements or elastification.

[0058] As used herein, the term "diaper" refers to an absorbent article generally worn by infants and incontinent persons that is worn about the lower torso of the wearer. It should be understood, however, that the present invention is also applicable to other absorbent articles such as incontinent briefs, incontinent undergarments, diaper holders and  
15 liners, feminine hygiene garments, and the like.

[0059] A preferred wipe for the purpose of this invention comprises an absorbent fibrous material or core into which the composition may be releasably incorporated. A highly preferred disposable wipe for the purposes of this invention comprises an absorbent fibrous material and a faeces-impermeable backing material; said backing being superposed or co-extensive with one face of said absorbent fibrous material; said backing material most preferably being a web-  
20 backing material and most preferably having a width greater than said absorbent material providing side marginal portions which extend beyond said absorbent material, said margin portions being folded around and on top of the edges of said absorbent material. The compositions of the invention agent may be releasably incorporated into the wipe structure by diverse methods which will be readily apparent to those skilled in the art. For example, the compositions can be present in aqueous or volatile carrier such as water, ethanol, or the like, or creams, lotions, oils, ointments, gels or pow-  
25 ders, and applied to the absorbent material by spraying, dipping, printing, soaking or otherwise contacting the absorbent material of the wipe with the lipase-inhibiting agent and its carrier. A skin cleansing agent, preferably an oleaginous cleansing agent, may optionally be releasably incorporated into the absorbent material as well.

[0070] The compositions of the present invention are preferably incorporated into a diaper, preferably into the absorbent core structure or most preferably into the topsheet structure. The composition may be incorporated into the diaper structure by diverse methods which will be readily apparent to those skilled in the art. For example, the composition can be, optionally after being dispersed aqueous or volatile carrier such as water, ethanol, or the like, applied to the diaper  
30 topsheet, to the absorbent core, or to the core side of the backsheet, by spraying, dipping, printing, soaking or otherwise contacting the selected structural element of the diaper with composition and optionally its carrier, which is called herein impregnation.

[0071] The diaper preferably comprises a liquid pervious topsheet, a liquid impervious backsheet joined with the topsheet, an absorbent core positioned between the topsheet and the backsheet. While the topsheet, the backsheet, and the absorbent core may be assembled in a variety of well known configurations, preferred diaper configurations are described generally in U.S. Patent 3,860,003 entitled "Contractable Side Portions for Disposable Diaper" which issued to Kenneth B. Buell on January 14, 1975; and U.S. Patent Application Serial No. 07/715,152, allowed, "Absorbent Article With Dynamic Elastic Waist Feature Having A Predisposed Resilient Flexural Hinge", Kenneth B. Buell et al. filed  
40 June 13, 1991.

[0072] The backsheet is positioned adjacent the garment surface of the absorbent core and is preferably joined thereto by attachment means such as those well known in the art. For example, the backsheet may be secured to the absorbent core by a uniform continuous layer of adhesive, a patterned layer of adhesive, or an array of separate lines, spirals, or spots of adhesive. Adhesives which have been found to be satisfactory are manufactured by H. B. Fuller Company of St. Paul, Minnesota and marketed as HL-1258. The attachment means will preferably comprise an open pattern network of filaments of adhesive as is disclosed in U.S. Patent 4,573,986 entitled "Disposable Waste-Containment Garment", which issued to Minetola et al. on March 4, 1986, more preferably several lines of adhesive filaments  
45 swirled into a spiral pattern such as is illustrated by the apparatus and methods shown in U.S. Patent 3,911,173 issued to Sprague, Jr. on October 7, 1975; U.S. Patent 4,785,996 issued to Ziecker, et al. on November 22, 1978; and U.S. Patent 4,842,666 issued to Werenicz on June 27, 1989. Alternatively, the attachment means may comprise heat bonds, pressure bonds, ultrasonic bonds, dynamic mechanical bonds, or any other suitable attachment means or combinations of these attachment means as are known in the art.

[0073] The absorbent article may further comprise elastification or closure features well-known in the art and - for  
55 example - described in E 0254476 (Alemay).

[0074] The topsheet is positioned adjacent the body surface of the absorbent core and is preferably joined thereto and to the backsheet by attachment means such as those well known in the art. As used herein, the term "joined" encompasses configurations whereby an element is directly secured to the other element by affixing the element

directly to the other element, and configurations whereby the element is indirectly secured to the other element by affixing the element to intermediate member(s) which in turn are affixed to the other element.

[0075] Generally, the topsheet is compliant, soft feeling, and non-irritating to the wearer's skin. Further, the topsheet is liquid pervious permitting liquids (e.g., urine) to readily penetrate through its thickness. A suitable topsheet may be manufactured from a wide range of materials, such as porous foams; reticulated foams; apertured plastic films; or woven or nonwoven webs of natural fibres (e.g., wood or cotton fibres), synthetic fibres (e.g., polyester or polypropylene fibres), or a combination of natural and synthetic fibres. There are a number of manufacturing techniques which may be used to manufacture the topsheet. For example, the topsheet may be a nonwoven web of fibres spunbonded, carded, wet-laid, meltblown, hydroentangled, combinations of the above, or the like.

[0076] The various core, topsheet and backsheet materials can be arranged in any way known in the art, such as described in Weisman et al. (EP 0 202 125) or Alemany et al. (EP 0 254 476).

[0077] Also encompassed in the present invention is a process for making a diaper comprising the composition of the invention whereby the topsheet is impregnated with the composition before incorporation in the diaper.

### 15 Process

[0078] Also encompassed in the invention is a process for reducing the lipolytic enzyme activity of the lipase enzymes present on the external skin, whereby the process comprises the steps of preferably topical, applying of the compositions of the invention to the external skin, or preferably topical, applying of a composition according to the invention to the external skin. reducing the pH to below 7.3, preferably below 6 or even 5.

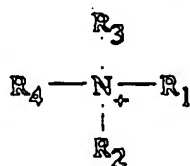
[0079] The composition used in the process or the process is preferably such that within the first 15 minutes after application of the compound or the composition to the affected area, the lipase enzyme activity is reduced to 35%, preferably 25%, more preferably less than 20% of the initial lipase activity in this area.

[0080] Preferably the composition used in the process or the process is such that 60 minutes after application of the composition to the affected area, the lipase enzyme activity is still less than 45%, preferably 35%, more preferably less than 30% of the initial lipase activity in this area.

[0081] This process can be also be done by applying an absorbent article which comprises the composition present in a suitable level, to the skin.

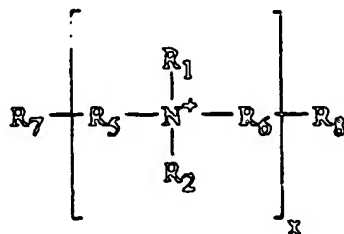
### 30 Claims

1. The use of one or more cationic compounds of formulas:



$M^-$  (I)

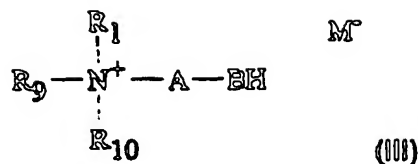
or



$M^-$

(II)

or an amphoteric compound and preferably an acidity source, the amphoteric compound having at its iso-electric point the formula:



- for preparation of a composition for prevention, treatment or reduction of lipolytic dermatitis to the external skin, wherein  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  are a  $C_1$ - $C_{22}$  alkyl, alkenyl, aryl, arylalkyl, amidoalkyl, (poly) alkoxy, hydroxyalkyl, or acyl groups, or two or more groups of  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  form together one or more ring structures;  $R_5$ ,  $R_6$  and  $A$  are independently a  $C_1$ - $C_{22}$  alkylene, alkenylene, (poly) alkoxy, hydroxyalkylene, arylalkylene or amido alkylene groups;  $R_7$  and  $R_8$  are independently a  $C_1$ - $C_4$  alkyl, alkenyl, alkoxy group or a hydroxy group or hydrogen;  $R_9$  and  $R_{10}$  are independently a  $C_1$ - $C_{22}$  alkyl, alkenyl, aryl, arylalkyl, amidoalkyl, (poly) alkoxy, hydroxyalkyl, or acyl groups, or two or more of the groups  $R_1$ ,  $R_9$  and  $R_{10}$  form together one or more ring structures;  $BH$  is a proton donating group;  $x$  is from 2 to 4; and  $M$  is a counter ion.
2. The use of a cationic compound for preparation of a composition according to Claim 1 wherein the composition is for prevention, treatment or reduction of lipolytic diaper rash.
  3. The use of a cationic compound for preparation of a composition according to Claim 1 or 2 wherein the cationic compound comprises one or more substituted  $R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ ,  $R_9$  or  $R_{10}$  groups and/ or a substituted  $R_5$  and/or substituted  $R_8$  group, whereby the substituent is selected from the group consisting of derivatives of silicon, glucose, fructose and saccharose.
  4. The use of a cationic compound for preparation of a composition according to any of Claims 1 to 3 wherein the cationic compound comprises at least one  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_9$  being  $C_1$ - $C_8$ , preferably  $C_1$ - $C_4$  alkyl, alkenyl or alkoxy groups, most preferably methyl or ethyl groups.
  5. The use of a cationic compound for preparation of a composition according to any of the preceding Claims, wherein the cationic compound comprises at least one  $R_1$ ,  $R_2$  or  $R_3$  or  $R_9$  being a poly alkoxy group.
  6. The use of a cationic compound for preparation of a composition according to any of the preceding Claims, wherein the cationic compound is of formula (III), being a betaine compound or sulfo-betaine compound
  7. A composition according to any preceding Claim, whereby the cationic compound is present at a level of from 0.01% to 90% by weight.
  8. A disposable absorbent article containing the composition according to any preceding Claim, whereby the cationic compound, comprised in the composition, is present at a level of from 0.01% to 10% by weight of the article.
  9. A disposable absorbent article containing the composition according to any of Claims 1 to 7 Claim at a level of from 0.01% to 10% by weight of the article.
  10. A disposable absorbent article according to Claim 8 or 9 in the form of a diaper or wipe.
  11. A disposable absorbent article according to Claim 10, whereby the diaper comprises a topsheet, containing the composition according to any of Claims 1 to 7.
  12. A cosmetic composition according to any of Claims 1 to 7 in the form of a cream lotion, gel, foam, oil, ointment or powder, which is substantially free from nonionic and/ or anionic surfactants and/ or phosphoric acid esters and/ or enzymes for topical application to the external.
  13. A cosmetic cream, lotion, gel, oil or powder according to Claim 12 wherein an acidity source is present.
  14. A process for reducing the lipolytic enzyme activity of lipolytic enzymes present on the external skin comprising the step of applying a composition or absorbent article comprising the composition according to any preceding Claim

to the external skin.

15. A process for making a diaper according to Claim 11, whereby the topsheet is impregnated with a composition according to any of Claims 1 to 7 prior to incorporation of the topsheet in the diaper.

5

10

15

20

25

30

35

40

45

50

55



European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number  
EP 97 12 0700

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.8)
X	WO 96 17681 A (THE PROCTER & GAMBLE CO.) 13 June 1996 * the whole document *	1-15	A61K31/00 A61K7/50 A61K7/00 A61L15/34 A61F13/15
X	DATABASE "CHEMICAL ABSTRACTS" (HOST: STN); Abs. 99: 141 503, Columbus, OH, USA; & JP 58 060 068 A(KAO CORP.) 9 APRIL 1983 XP002066466 * the whole document *	1-15	
X	DATABASE "CHEMICAL ABSTRACTS" (HOST: STN); Abs.104: 188 122, Columbus, OH, USA; & JP 60 215 870 A(KAO CORP.) 29 OCTOBER 1985 XP002066467 * the whole document *	1-15	
X	DATABASE "CHEMICAL ABSTRACTS" (HOST: STN); Abs.127: 55 935, Columbus, OH, USA; & JP 09 157 172 A(LION CORP.) 17 JUNE 1997 XP002066468 * the whole document *	1-7, 12-14	TECHNICAL FIELDS SEARCHED (Int.Cl.8)  A61K
X	US 5 240 562 A (D. PHAN ET AL.) 31 August 1993 * the whole document *	1-11	
X	US 5 141 803 A (D. PREGOZEN) 25 August 1992 * the whole document *	1-15	
X	EP 0 688 901 A (KIMBERLY CLARK CORP.) 27 December 1995 * the whole document *	1-15	
		-/--	
The present search report has been drawn up for all claims			
Place of search <b>THE HAGUE</b>		Date of completion of the search <b>29 May 1998</b>	Examiner <b>G11kman, J-F</b>
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1503 03/82 (P/AC01)



European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number  
EP 97 12 0700

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	EP 0 613 675 A (JOHNSON & JOHNSON CONSUMER PROD., INC.) 7 September 1994 * the whole document *	1-15	
X	US 4 943 350 A (L. BOGART ET AL.) 24 July 1990 * the whole document *	1-15	
X	WO 97 30217 A (KAYSERSBERG) 21 August 1997 * the whole document *	1-15	
X	DE 14 67 835 A (CHEMOFORMA AG) 5 December 1968 * page 3, line 2-4; claim 1; example 1 *	1	
			TECHNICAL FIELDS SEARCHED (Int.Cl.8)
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 29 May 1998	Examiner Glikman, J-F
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons &amp; : member of the same patent family, corresponding document</p>			

EPO FORM 1503 (03/82) (P04/C01)

**THIS PAGE BLANK (USPTO)**